SPOTLIGHT ON MARYLAND

MARYLAND HEALTH CARE COMMISSION

Asthma Could Be More Effectively Managed for Many Privately Insured Children in Maryland

Asthma is the most common chronic disease in children and adolescents, and its prevalence has been increasing since the early 1980s.[1] In Maryland, 8.6% of children currently have asthma, and 11.1% have a history of asthma.[2] Nationwide, about 13 percent of children under age 18 have been diagnosed with asthma.[3] Although it is treatable, asthma is often misdiagnosed or undertreated by health care professionals. Uncontrolled asthma results in significant monetary and social costs.[4] It is associated with high emergency department use, hospitalizations, and even mortality. A leading cause of school absences, uncontrolled asthma makes children less able to participate in other educational, recreational and social activities. Parents/caregivers lose time from their work and other activities to care for these children. And nighttime asthma symptoms interfere with sleep, which decreases productivity at school for children and at work for their parents/caregivers.

In an effort to reduce asthma morbidity and mortality, the National Asthma Education and Prevention Program (NAEPP), under the auspices of the National Heart, Lung and Blood Institute, developed expert guidelines for the diagnosis and management of asthma.[5,6] Many of the complications caused by asthma could be averted if persons with asthma and their health care providers managed the disease according to established guidelines. Increasing the percentage of asthma patients who receive appropriate diagnosis and treatment is one of the performance goals in *Healthy People 2010*.[7] To help further the treatment component of this goal, the Maryland Health Care Commission (MHCC) conducted a study of asthma medication use among privately insured children with an asthma diagnosis to assess compliance with the NAEPP guidelines. The data come from 2003 and the children had private insurance coverage for both professional services and medications, which should have facilitated their having appropriate asthma management. The level of guideline compliance can be used as both a measure of the quality of asthma care and as a baseline for assessing future improvements.

Medication Guidelines

The NAEPP guidelines define four classifications of pediatric asthma severity: mild intermittent, mild persistent, moderate persistent, and severe persistent. The asthma medication component of the guidelines advocates daily use of anti-inflammatory medications **(controller medications)** as maintenance drugs for control of persistent asthma; mild intermittent asthma does not need controller medication. Inhaled short-acting beta$_2$-agonists are to be used as **rescue medications** for treatment of acute symptoms only (in either persistent or intermittent cases).[8]

In the 2002 update to the guidelines, the NAEPP Expert Panel concluded that among the controller medications, "none ... is as effective as inhaled corticosteroids in improving asthma outcomes."[6,9] The guidelines were revised to make *inhaled corticosteroids the preferred first-line anti-inflammatory medication* for treating persistent asthma.[10] The guidelines emphasize a step-wise approach to treatment guided by the severity of the disease: at higher severity levels, the dose of inhaled corticosteroids is increased and/or long-acting beta$_2$-agonists *(LABA)* are used along with the inhaled corticosteroid (*IC*).[11] The preferred treatment for mild persistent asthma is an *IC*; other controller medications - mast cell stabilizers (cromolyn, nedocromil), theophylline, and leukotriene modifiers - are non-preferred alternatives at this level of severity.[12] (The expected percentage of children with persistent asthma who could/should be on one of the non-preferred alternative controllers in lieu of an *IC* is less than 5%.[13]) For moderate asthma, an *IC* plus *LABA* is the preferred medication regime; non-preferred substitutes for the *LABA* are theophylline and leukotriene modifiers.[14] In severe persistent asthma, there are no alternatives to the recommended high-dose *IC* plus *LABA*.[15]

Study Design

The purpose of this study is to provide information on the quality of asthma care received by privately insured children in Maryland by assessing adherence to NAEPP medication guidelines. Data for the study come from MHCC's Medical Care Data Base and are for 2003.[16] The children screened for the study had coverage for both professional care and prescription drugs and were ages 5-17 years. The selection criteria (detailed in the **Technical Notes** at the end of this issue brief) identified 2,830 children with a current asthma diagnosis. Although the severity of asthma and whether or not asthma symptoms were under control cannot be directly

measured without detailed clinical data, the prescribing data allowed us to infer a limited classification of severity (mild intermittent or some level of persistent), and to assess if rescue medications were being overused (i.e., uncontrolled asthma). The prescription data also enabled us to determine whether the controller medications received complied with the guidelines.[17]

Asthma-related prescription drugs dispensed by pharmacies throughout the year for these children were categorized as either rescue or controller medications. Controller medications were compared with NAEPP medication guidelines in terms of the drug classes received: *IC, LABA,* or non-preferred *Other*, which includes leukotriene modifiers, mast cell stabilizers, or theophylline. We did not evaluate the amount of controller medication received. Overuse of rescue medications served as the indicator for uncontrolled asthma. Overuse was defined as more than two prescriptions for a rescue medication during the year, in accordance with the "Rules of Two".[18]

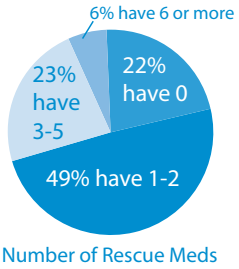
According to the NAEPP guidelines, mild intermittent asthma can be controlled without daily medication (i.e., controller medication), but all levels of persistent asthma require daily medication for asthma control. Therefore, children in the study who appeared to have their asthma under control (as evidenced by receipt of less than three prescriptions for rescue medications) without any apparent use of controller medications were inferred to have mild intermittent asthma. All other children - those who received at least one controller prescription or should have received a controller prescription (based on their excessive rescue medication use) - were inferred to have some level of persistent asthma. If a child with mild intermittent asthma happened to receive a controller medication, this assignment system misclassified the child as having controlled, persistent asthma. However, given that the evidence points to a general under use of controllers in the treatment of children with asthma, this type of misclassification is likely to have been rare.

How Key Concepts Are Defined in the Study

Controlled Asthma – when fewer than three rescue drug prescriptions were filled in the year.
Uncontrolled Asthma – when three or more rescue drug prescriptions were filled in the year.
Severely Uncontrolled Asthma – when six or more rescue drug prescriptions were filled in the year.
Mild Intermittent Asthma – when no controller drugs and less than three rescue drug prescriptions were filled in the year.
Persistent Asthma – when at least one controller drug prescription or three or more rescue drug prescriptions were filled in the year.

Asthma is uncontrolled in more than one fourth of privately insured children with asthma.

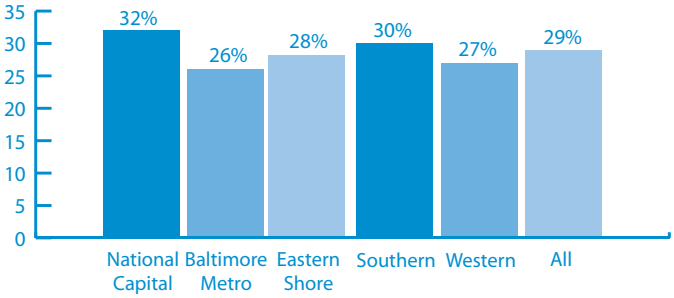
Figure 1: Percent of Privately Insured Asthmatic Children Prescribed Rescue Medications, 2003



Of the children between the ages of 5 and 17 years with asthma that were identified for this study, 29% received three or more prescriptions for rescue medication during the year, indicating that their asthma symptoms were not under control (Figure 1). One-fifth of the uncontrolled – 6% of all children in the study – collected six or more rescue prescriptions during the year, indicating that their symptoms were severely uncontrolled. Children with controlled and uncontrolled asthma were similar in terms of age distribution, with over one-half in each group between the ages of 5 and 10 years.

The proportion of privately insured children with uncontrolled asthma varied slightly across the state, ranging from 26% to 32% (Figure 2). Children residing in the National Capital Area had a higher rate of uncontrolled asthma than those living in the Baltimore Metropolitan area.[19] (Region definitions are in the **Technical Notes.**) However, there was no evidence of an urban-rural difference in control rates. Rates of uncontrolled asthma in the more rural areas (Eastern Shore, Western, and Southern Maryland) were not statistically different from those in the metropolitan areas. Regionally, rates of severely uncontrolled asthma did not vary significantly (data not shown).

Figure 2: Percent of Privately Insured Asthmatic Children with Uncontrolled Asthma by Region, 2003

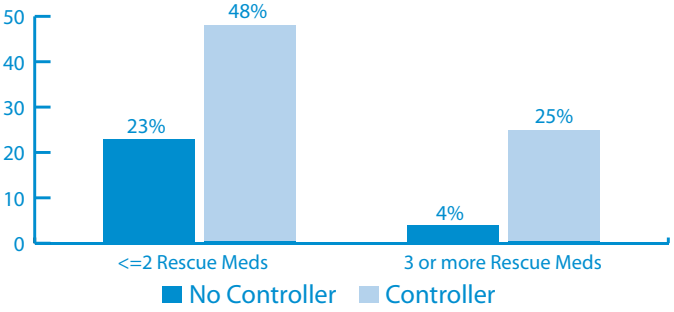


27% of the children with asthma received no controller medications.

About one-fourth of the asthmatic children (23% + 4%) received no controller medications during the year (Figure 3). Most of these – 23% of the children – appeared to have their asthma under control since they received fewer than three rescue medication prescriptions. This group likely represents cases of mild intermittent asthma, which,

according to the guidelines, does not require daily use of controller medications to keep asthma symptoms under control. However, some of the children who received no controller medications had uncontrolled asthma. They constituted just 4% of all children with asthma, but accounted for 13% of the uncontrolled group.[20]

Figure 3: Percent of Privately Insured Asthmatic Children Prescribed Controller and Rescue Medications, 2003

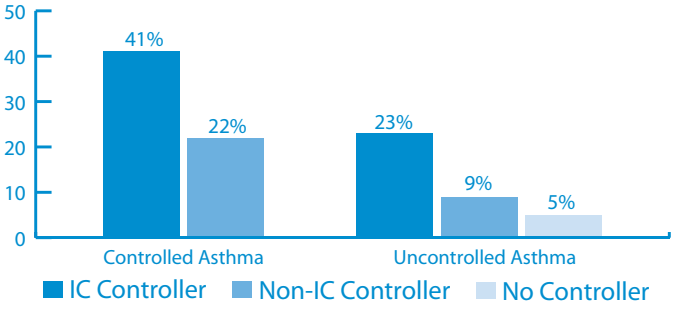


More than one-third of children with uncontrolled asthma did not receive an inhaled corticosteroid for symptom management.

The preferred treatment for managing symptoms of persistent asthma consists of inhaled corticosteroids *(IC)* with the addition of long-acting beta$_2$-agonists *(LABA)* in cases of moderate or severe asthma, as described under **Medication Guidelines.** The guidelines list several alternatives for the *IC* in treating mild persistent asthma, but because these medications are ranked below *ICs* in effectiveness, they are *non-preferred* alternatives.[21] We assessed each child with persistent asthma (**Key Concepts** box) to determine whether they had received any controller medications during the year and whether the controller medications included the preferred treatment of using an *IC* anti-inflammatory drug. (Since we could not define severity among the apparent cases of persistent asthma, preferred treatment was broadly defined as receipt of at least one *IC* during the year.) If physicians were prescribing in accordance with NAEPP medication guidelines, we would expect nearly all children with persistent asthma to have received an *IC*, with fewer than 5% receiving a non-preferred alternative medication in place of the *IC*.

Among the children who were classified as having persistent asthma, 36% did not receive an *IC* during the year, with 5% receiving no controller medications and 31% (22% + 9%) receiving a non-*IC* controller medication (Figure 4). The vast majority of those obtaining a non-*IC* controller (29%) received one of the non-preferred alternatives, almost exclusively a leukotriene modifier *(LM)*.[22] The remaining 2% received a *LABA* only, which is not included as an alternative treatment for any category of severity. Overall, 37% of the children with persistent asthma were classified as having uncontrolled asthma.

Figure 4: Percent of Privately Insured Children with Persistent Asthma Prescribed Controller Medication, 2003

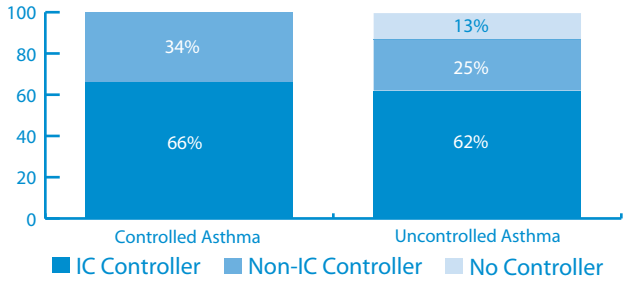


Note: IC refers to Inhaled Corticosteroids.

Among those with uncontrolled persistent asthma (37% of the persistent asthma cases), 38% did not receive the preferred medication, with 13% receiving no controller medication and 25% receiving a non-*IC* (i.e., non-preferred) controller (Figure 5). These children have uncontrolled asthma symptoms, and an *IC* could potentially control their symptoms and enhance their quality of life.[23] The majority of those who appear to have uncontrolled asthma (62%) did receive at least one *IC* prescription during the year but apparently needed more aggressive medication therapy: more days and/or higher dosages of an *IC* or the addition of a second medication (such as a *LABA*) in a suitable dosage.

Among those with persistent but controlled asthma - who all received controller medications - the majority (66%) received the preferred *IC* controller (Figure 5). However, 34% of the children with controlled persistent asthma received a non-preferred controller medication (predominately a *LM*). Assuming physician compliance with the NAEPP medication guidelines, which prefer use of *ICs* over other types of controller medications, we would expect fewer than 5% of these children to have received a non-*IC* controller. The high level of non-*IC* controller use in this group - more than 6 times the expected level - indicates that treatment for persistent asthma often does not correspond to best practices even among those whose asthma appears to be in control.

Figure 5: Treatment of Privately Insured Children with Persistent, Controlled (or Uncontrolled) Asthma Prescribed Controller Medication, 2003



Note: IC refers to Inhaled Corticosteroids.

Study Limitations

This assessment was based on prescriptions collected by the patients, representing an amalgam of physician and patient behavior. It is possible that selective redemption of prescribed medication by the patients may conceal greater receipt of *IC* prescriptions than our study results indicate. Alternatively, our method of allowing receipt of one *IC* prescription during the year to count as compliance with the NAEPP guidelines may overestimate compliance. If we had employed a daily dose methodology to determine if the prescription dosage achieved the minimum *IC* dosing level recommended in the guidelines, we might have identified more cases of deviation from the guideline recommendations. Additionally, the NAEPP guideline's step-wise approach to treatment requires that the medication regimes for children with higher disease severity levels employ higher doses of an *IC* and/or include an *LABA* (with the short-term addition of an oral corticosteroid, if necessary) to bring the asthma under control. At least some of the children who received an *IC* but appear to have uncontrolled asthma are likely to be cases of noncompliance from the perspective of the guideline's step-wise approach to asthma control.

Because we did not have information on asthma symptoms, severity of illness regarding the classification of mild intermittent versus persistent asthma cases was inferred from receipt of controller and/or rescue medications, and controlled/uncontrolled asthma status was inferred from the number of rescue medication prescriptions. Some of the children who appear to have controlled asthma, based on number of rescue medications received, might have been labeled as uncontrolled if our assessment had included urgent care visits/hospitalizations for asthma or frequency of asthma symptoms. Another possible misclassification is mild intermittent asthma being classified as controlled, persistent asthma if the child happened to receive a controller medication; given the evidence on under use of controllers in the treatment of children with asthma, this type of misclassification is likely to be rare.

Discussion

Appropriate treatment with asthma medications can control asthma symptoms in children, improving the quality of their lives (and that of their parents/care givers) and reducing the costs associated with uncontrolled asthma, such as emergency department and inpatient hospital care. The NAEPP medication guidelines were created to improve the likelihood that asthma would be treated in accordance with best practices by all professionals, whether primary care physicians or specialists. In 2002, the Expert Panel, citing evidence that no alternative controller medication had been found to be as effective as inhaled corticosteroids in improving asthma outcomes, updated the guidelines to make inhaled corticosteroids (*IC*) the preferred controller medication (alone or in combination with a second medication) for children and adults with asthma. If physicians adhere to the NAEPP guidelines' recommendation of an *IC* controller in the case of persistent asthma[24], all children identified as having persistent asthma should be using a controller medication daily, and use of non-preferred controller medications (in lieu of an *IC*) should occur in less than 5% of the children.

Our analysis of privately insured (including drug coverage) children with asthma in 2003 found significant levels of both uncontrolled asthma and non-preferred controller medication use. In spite of their preferred insurance status, more than one-third (37%) of the privately insured children with persistent asthma appeared to have uncontrolled asthma. Most of the children with uncontrolled asthma did receive at least one *IC* during the year, but apparently needed to have their medication regime adjusted: more days or higher dosages of the *IC* medication or the addition of a second medication (e.g., *LABA*), as indicated in the step-wise approach to asthma management laid out in the guidelines.

Use of non-preferred controllers was much higher than expected: 31% of the children identified as having persistent asthma received a non-preferred controller (predominately a *LM*) rather than an *IC*. This substitution occurred in both uncontrolled and controlled persistent asthma cases. Use of an alternative controller in lieu of the preferred *IC* medication by children with uncontrolled asthma is clearly a cause for concern, given the health implications and costs associated with uncontrolled asthma. But even among the controlled asthma cases, the unexpectedly high level of non-preferred controller use is an issue because it indicates that many physicians in Maryland are not prescribing in accordance with the NAEPP guidelines' clear preference for *ICs* over other controller medications. That these children appear to have their asthma under control by our limited criteria does not change the fact that they are not receiving what the NAEPP Expert Panel has determined to be "the treatment of choice for the most effective long-term control of asthma."[25]

Lack of asthma control and evidence of nonadherence to the NAEPP medication guidelines in the treatment of asthma are widely acknowledged[26], which explains why *Healthy People 2010* has a goal for increasing the percentage of asthma patients who receive appropriate diagnosis and treatment. The treatment problem is not simply related to a lack of guideline awareness among physicians. Significant numbers of physicians who are aware of the guidelines, can demonstrate their understanding of the guidelines in written tests, and rate themselves as high in guideline compliance do not, however, conform to best practices in treating their patients.[27]

Providers could likely benefit from more direct and detailed feedback on whether their prescribing practices for asthma conform to best practices and whether their patients are exhibiting signs of uncontrolled asthma, such as excessive use of rescue medications or urgent care (emergency room or inpatient) to treat their asthma. The Health Plan Employer Data and Information Set (HEDIS) includes a quality measure for asthma care defined as "use of appropriate medications for people with asthma," but patient-specific data is generally not shared with the managing physician. The HEDIS measure is also limited in that it indicates only whether or not a patient with asthma received at least one anti-inflammatory drug on the NAEPP guidelines during the year. It does not indicate if that drug was the preferred inhaled corticosteroid or if the volume of controller medications received met the recommended minimum daily dosage, nor does it measure the volume of rescue medications obtained by the patient. The last measurement has been included by the California Asthma Collaborative – a group of 11 Medicaid managed care plans – as one of their asthma measures, along with the HEDIS measure and the number of asthma-related inpatient admissions (and days) and emergency department visits. Providers whose patients exhibit excess rescue medication use are targeted for an educational intervention.[28]

The results of this study provide a baseline to measure efforts by Maryland's physician, insurer and public health communities to improve the treatment of asthma. It is our intention to reproduce and refine this study in the future to assist in the campaign to control asthma in Maryland's children.

Acknowledgements

This issue brief was produced by a team that included staff from the Maryland Health Care Commission's Center for Information Services & Analysis and from outside contractors: Janet Sutton, of NORC; and Adrian Ndikumwami, of Social & Scientific Systems, Inc. Important contributions also came from two uncompensated team members: Carol J Blaisdell, MD, Associate Professor of Pediatrics and Physiology and Chief, Division of Pediatric Pulmonology/Allergy at the University of Maryland School of Medicine; and Wendy G Lane, MD, MPH, Assistant Professor, Department of Epidemiology & Preventive Medicine and Department of Pediatrics at the University of Maryland School of Medicine, and Asthma Epidemiologist, Maryland Asthma Control Program. Dr. Blaisdell provided the study question and assisted with the study design and the medication lists. Both Dr. Blaisdell and Dr. Lane commented on analytical results (prompting revisions in the study) and reviewed drafts of the brief. Their generous contributions are deeply appreciated by the other members of the team.

Technical Notes

Identification of Privately Insured Children with Asthma: Children were determined to have asthma if they had at least 2 claim records--at least 7 days apart--during the first quarter of 2003, each with an evaluation and management (E&M) CPT code and each with at least one diagnosis (ICD-9) code in the range 493.0 - 493.9. Children with a diagnosis of cystic fibrosis (ICD-9 277.0-277.01) were excluded. Children identified as having asthma in the MCDB but having no prescription drug records (either for asthma or for other conditions) were excluded from the analysis.

Counting of Prescriptions: Number of prescriptions was "normalized," with each 30-day supply counting as one prescription fill.

Definitions of Regions in Maryland: National Capital: Montgomery and Prince George's; Baltimore Metropolitan: Anne Arundel, Baltimore, Carroll, Harford, and Howard counties, plus Baltimore City; Western: Allegany, Frederick, Garrett, and Washington; Southern: Calvert, Charles, and St. Mary's; Eastern Shore: Caroline, Cecil, Dorchester, Kent, Queen Anne's, Somerset, Talbot, Wicomico, and Worcester.

Questions regarding this study may be sent to Linda Bartnyska at lbartnyska@mhcc.state.md.us.

---

[1] National Asthma Education and Prevention Program, Heart Lung and Blood Institute. Data Fact Sheet: Asthma Statistics. U.S Department of Health and Human Services, Public Health Service, 1999.

[2] Maryland Asthma Control Program. Asthma in Maryland, 2004. Baltimore, MD: State of Maryland Department of Health and Mental Hygiene, Family Health Administration.

[3] Bloom B, Cohen RA, Vickerie JL, Wondimu EA. Summary Health Statistics for U.S. Children: National Health Interview Survey, 2001. National Center for Health Statistics. Vital Health Statistics 10(16), 2003.

[4] American Academy of Allergy, Asthma and Immunology. Pediatric Asthma: Promoting Best Practices. http://www.aaaai.org/members/resources/initiatives/pediatricasthma.stm. Accessed April 2006.

[5] National Asthma Education and Prevention Program, Heart Lung and Blood Institute. Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma. NIH Publication No. 97-4051, July 1997.

[6] National Asthma Education and Prevention Program, Heart Lung and Blood Institute. Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma – Update on Selected Topics 2002. NIH Publication No. 02-5074, June 2003.

[7] U.S. Department of Health and Human Services. *Healthy People 2010.* 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000. http://www.health.gov/healthypeople. Accessed April 2006.

[8] Short acting beta$_2$-agonists that serve as rescue medications

(inhaled) include albuterol, levalbuterol, metaproterenol, pirbuterol, and dipratropium.

[9] Measured outcomes included: prebronchodilator forced expiratory volume in 1 second (FEV_1); reduced hyperresponsiveness; improvements in symptom scores; fewer courses of oral corticosteroids; and fewer urgent care visits or hospitalizations.

[10] Examples of *ICs* are beclomethasone, budesonide, fluindolide, fluticasone, and triamcinolone.

[11] *LABA* in an inhaled form (longer lasting, fewer side effects than tablet forms) includes salmeterol and formoterol; the tablet form is albuterol in an extended release formulation. The drug Advair combines an *IC* (fluticasone) and a *LABA* (salmeterol) in a single medication.

[12] Mast cell stabilizers (e.g., cromolyn, nedocromil) and leukotriene modifiers (e.g., montelukast, zafirlukast) are anti-inflammatories; theophylline is a bronchodilator.

[13] Estimate provided by Dr. Carol Blaisdell, Director of Pediatric Pulmonology at the University of Maryland Medical Center.

[14] A higher dose of *IC* without the *LABA* is another non-preferred alternative.

[15] Short-term use of systemic corticosteroids may be added, if needed, to obtain control.

[16] Data for this study are based on services and payments captured in the Prescription Drug Component of the Medical Care Data Base (MCDB), which includes insurance claim records of non-institutional and professional services rendered by physicians and non-physician health care professionals to patients who live in Maryland. Insurance companies and HMOs meeting certain criteria, namely, that they are licensed in Maryland and collect more than $1 million in health insurance premiums, are required to submit information to MHCC under the Code of Maryland Regulations (COMAR) 10.25.06. However, if an employer, such as the State of Maryland, contracts directly with a pharmacy benefit manager, rather than an insurer, for drug coverage then that use is not included in the MCDB. Lacking an enrollment file, the only way to identify persons with prescription drug coverage is to require that they have at least one drug claim in the MCDB. The drug data includes both retail store and mail order prescriptions.

[17] These criteria were developed using the NAEPP diagnosis & medication guidelines in consultation with Dr. Carol Blaisdell, Director of Pediatric Pulmonology at the University of Maryland Medical Center.

[18] "Rules of Two" is a registered service mark of Baylor Health Care System. It lists four alternative criteria that indicate a patient's asthma is out of control. http://www.baylorhealth.com/medicalspecialties/asthma/asthmaprograms.htm.

[19] Chi-square test statistic with p=.0334; Marascuillo procedure was used to test pairwise comparisons and indicated the only significant difference was between the extreme percentages.

[20] Due to rounding, the percentages in Figure 4 yield 14%, but 13% is the correct value.

[21] The guidelines also list non-preferred alternatives for the *LABA* in the *IC+LABA* medication regime for treatment of moderate asthma, but we did not evaluate drug combinations in this study.

[22] The popularity of leukotriene modifiers may stem from the fact that they are pills and do not have to be inhaled like the corticosteroids.

[23] 40% of the children with persistent asthma who did not receive an *IC* (i.e., 14%/36%) had uncontrolled asthma.

[24] The guidelines indicate that severe, and possibly moderate, persistent asthma require a second controller (*LABA* recommended) to be combined with the *IC*.

[25] Stanton MW, Dougherty D, Rutherford MK. Chronic care for low-income children with asthma: strategies for improvement. Rockville (MD): Agency for Healthcare Research and Quality; 2005. Research in Action Issue 18. AHRQ Pub No. 05-0073.

[26] Carlton BG et al. The status of asthma control and asthma prescribing practices in the United States: Results of a large prospective asthma control survey of primary care providers. *Journal of Asthma.* 2005; 42:529-535.

[27] Veniga CC et al. Comparison of indicators assessing the quality of drug prescribing for asthma. *Health Services Research.* 2001; 36(1):143-161.

[28] Reller J, Center for Health Care Strategies (CHCS). Using a multi-stakeholder collaborative to improve asthma care for the Medicaid Population in California. Presented July 19, 2005 at Translating Research into Practice Conference, Washington DC.